



Department of Pesticide Regulation



Mary-Ann Warmerdam
Director

Arnold Schwarzenegger
Governor

California Notice 2006-06

TO: PESTICIDE REGISTRANTS AND DATA SUBMITTERS

SUBJECT: FORMAT GUIDELINES FOR DATA SUBMITTED TO SUPPORT
PESTICIDE PRODUCT REGISTRATIONS IN CALIFORNIA

When submitting scientific data to the Department of Pesticide Regulation, please follow the guidelines described below. These guidelines specify the format and organization of each data volume and include requirements for folders, covers and labels. Submissions that do not conform to these guidelines will be returned or held until they are prepared for processing. The Pesticide Registration Branch (PRB) does not have the facilities to hole-punch and bind submissions. If inappropriately bound submissions are received, the data sender has three choices: (1) re-send the data in the correct format; (2) collect the data, have it bound correctly, and return it to PRB; or (3) pay for PRB to return the submission.

The following guidelines are based on the federal regulations, Title 40 Code of federal Regulations, section 158.32, with some specific prohibitions and recommendations for California only. **All submissions that include data should have the data prepared in accordance with the following guidelines.** Do not bind applications for registration, labels, or proof of federal registration. Bind only the data and copies of your cover letter.

MAILING/SHIPPING ADDRESSES for the Pesticide Registration Branch:

If you are using the U.S. Postal Service, please mail to:

Department of Pesticide Regulation
Pesticide Registration Branch
P.O. Box 4015, 1001 I Street
Sacramento, California 95812-4015

If you are using any other carrier (U.P.S., Federal Express, etc.), please mail to:

Department of Pesticide Regulation
Pesticide Registration Branch
1001 I Street
Sacramento, California 95812-2828



FORMAT SPECIFICATIONS FOR DATA SUBMITTED TO PRB:

- ALL DATA MUST BE APPROPRIATELY BOUND!
- Conditional and supplemental data must be bound.
- Submit only one complete copy of the data.
- Use uniform 8-1/2 by 11 inch white paper, printed in black ink, with high contrast and good resolution.
- Do not include frayed or torn pages, carbon copies, or copies in other than black ink.
- Be sure that photocopies are clear, complete, and fully readable.
- Be sure that all pages are present, numbered, and in order.
- Do not include oversized computer printouts or fold-out pages.
- If the original report is not in English, provide a complete English translation.
- Separate types of studies must be bound in separate volumes (only one type of study per volume).
- Multiple small studies of similar type may be bound together in one volume, with tabs and divider pages between each study (e.g., several efficacy studies). Include a table of contents and bind to a maximum thickness of one and a half inches (about 345 pages).
- Separate similar studies or sections of studies by labeled tabs. Identify each study by the U.S. Environmental Protection Agency (U.S. EPA) guideline reference number and Master Record Identification Number (MRID).
- For large submissions, include a table of contents, or itemize the volume titles in your cover letter.
- Your cover letter should, at a minimum, include the following information:
 1. Name and address of data submitter(s);
 2. Reason why this package is being submitted to California;
 3. Date of submission; and
 4. List of submitted studies by title.

- **Place a copy of the cover letter in the front of each volume of the submission. The original cover letter should be bound in the front of the first volume, and copies bound in the front of all other volumes.**
- Any studies conducted on other than pesticide active ingredients or product formulations (e.g., inert ingredients, precursors, impurities, degradation products, etc.) must be clearly identified as to the kind of study (e.g., acute oral LD50), the compound on which the study is conducted, and the reason for its inclusion in this submission (e.g., to support registration of product XYZ, EPA Reg. No. 123-456-AA).
- If your submission is in response to a data call-in, reevaluation, risk assessment, or is an adverse effects disclosure, please label it prominently, identifying the specific reason for the submission. Please do NOT include any data in the submission that does not relate to the specific purpose of the submission.
- If your submission is a "courtesy copy" to PRB of data you submitted to U.S. EPA, please include a copy of your cover letter to U.S. EPA along with your own cover letter to PRB, telling us what product(s) or active ingredient(s) this submission is to support.
- If a single study consists of several volumes, clearly identify each volume in order (i.e. 1 of 5, 2 of 5, etc.) and bind a copy of the cover letter in the front of each volume.

RECOMMENDED ORDER FOR EACH STUDY VOLUME CONTENTS:

Front cover;
Copy of cover letter to PRB;
Title page;
Abstract (no confidential information);
Introduction;
Materials and Methods;
Results and Discussion;
Summary of Study;
Data, tables, appendices;
Analytical methods, feed analyses, etc.
Back cover.

Please DO NOT remove or move "confidential" information from where it occurs in a study.

SPECIFICATIONS FOR FOLDERS AND COVERS:

Please do NOT use the following:

- Plastic or vinyl covers of any sort (they tear, slide, and have a very short shelf-life);
- 2-, 3-, or 4-ring binders;
- Folders with pockets,
- Folders with comb-type, spiral-type or "velo"-type bindings (these do not allow the insertion of additional pages);
- Construction paper covers,
- Plain paper covers.

Please DO:

- Use "ACCO-PRESS" (or equivalent) pressboard folders (NOT plastic or vinyl) with holes punched in the left-hand 11-inch side of the pages.
- **Have folder prongs open in the front of the volume and please do NOT put tape on the prongs or bend them back.**
- If a study exceeds one and a half inches in thickness (about 345 pages), PLEASE divide it into the appropriate number of ACCO-PRESS type folders with a copy of the cover letter in each. Allow at least one-half inch of length on each of the ACCO-PRESS folder prongs for the addition of internal documents.
- Punch holes in the left side of the pages with sufficient margins so that the pages do not tear out easily.

SPECIFICATIONS FOR STUDY VOLUME LABELING:

Please clearly label each volume, including the following information:

- Name of data submitter,
- Product brand name and U.S. EPA Registration Number or active ingredient name,
- Type of data in the volume (e.g., chemistry, efficacy),
- Study title (e.g., acute oral LD50 in rats), and
- Number of volumes in the entire submission (e.g., 1 of 27, 2 of 27, etc.).

If the submission is in response to a specific PRB request, be sure to include the reason for submission on the label (e.g., SB-950 data call-in).

SUBMISSIONS NOT REQUIRING BINDING:

- An application for registration with labels, cover letter, and proof of federal registration. NO DATA SUBMITTED.
- A request for registration of an amended label with no data submitted.
- A request for registration of an alternate or revised formulation with no data submitted.
- Copies of correspondence, material safety data sheets (MSDS), or technical bulletins.

ELECTRONIC DATA SUBMISSIONS- NEW ACTIVE INGREDIENTS

DPR is requesting that applicants for registration of new pesticide products containing new active ingredients submit both a hard copy and an electronic copy of all required data. Please use Adobe Portable Document Format (PDF) as the standard file format and compact disks (CDs) as the transport medium. The disk must be compatible with Windows 95 or higher. Do not use floppy disks. Please use the same file formats, naming conventions, fonts, conversion options, etc. suggested by U.S. EPA. Refer to U.S. EPA's website at http://www.epa.gov/oppfead1/eds/pdf-spec_e-study.pdf for document titled "Specifications for Creating PDF Version of Study Reports". This document describes page size, margins, and font size for the original source document. It also details how to format and create a PDF file. Another useful document titled "Software Settings for the Creation of PDF Files for Electronic Submission" can be located at http://www.epa.gov/oppfead1/eds/softset_study.pdf.

Your cooperation in following these guidelines is very much appreciated. If you have any questions regarding these guidelines, please e-mail Ms. Jacquelyn Rivers at JRivers@cdpr.ca.gov, or call her at (916) 324-3571.

Original signed by Barry Cortez

3-1-06

Barry Cortez, Chief
Pesticide Registration Branch
(916) 445-4377

Date

cc: Ms. Jacquelyn Rivers